

## **REMARKS**

Claims 1-9 and 11-20 are currently pending. In the Office Action mailed March 17, 2008 (“Office Action”) claims 1-9 and 11-20 were rejected. Though this amendment claim 20 is amended and new claims 21-22 are added without introducing new subject matter. Applicants respectfully request reconsideration and allowance of the claims in light of these remarks.

### **Claim Rejections**

#### **35 USC 112**

Claim 20 was rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. More specifically, the Examiner suggests that support for “the step of performing neuromonitoring while the device is used to retract a surgical worksite,” cannot be found in the in the originally filed disclosure. The Applicants respectfully disagree. To comply with the written description requirement of 35 USC 112, first paragraph, each claim limitation must be expressly, implicitly, or inherently, supported in the originally filed disclosure. The requirement is satisfied if the patent specification describes the claimed invention in sufficient detail such that that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See MPEP 2163.*

The specification, as filed, is replete with discussion of monitoring neural structures while performing the steps of distraction and/or retraction. By way of example, the Examiner is pointed to paragraph [0014] (paragraphs are referenced according to the US Patent Application Publication corresponding to the present application- US2008/0097164) which teaches that both the distraction assembly and retraction assembly may be equipped with one or more electrodes for use in detecting one or more of the existence, distance, and direction of neural structures during “tissue distraction and/or **retraction**.” Again in paragraph [0040], the specification, as filed, indicates that the invention is directed to an “access system and related methods for creating and maintaining an operative corridor to the surgical target site, and optionally detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and/or after this process (including the steps of distraction and/or **retraction**).” Paragraph [0041] follows by teaching that “[N]eural monitoring may be accomplished via any number of suitable fashions,” including, but not limited to observing visual twitches, traditional EMG, and

surgeon-driven EMG. The Applicants respectfully submit that in light of any one of these referenced paragraphs (or any of paragraphs [0044], [0053], and [0057]-[0061], among others, also discussing in various detail the use of neuromonitoring during distraction and retraction), a person of skill in the art would more than reasonably conclude that that the Applicants were in possession of the claimed invention, or more specifically, that the Applicants were in possession of “the step of performing neuromonitoring while the device is used to retract a surgical worksite.” As such, the Applicants request that the rejection under 35USC112, first paragraph, be withdrawn.

Claim 20 was further rejected under 35 USC 112, 2<sup>nd</sup> paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggested that “it is not clear what the claimed ‘result of said neuromonitoring’ is,” and further that “the result” lacks sufficient antecedent basis.

The primary purpose for the definiteness requirement is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. *MPEP 2173*. Claim 20 has been amended such that the limitation “the result” has been changed to “a result,” such that Claim 20 now includes, in pertinent part, the steps of “performing neuromonitoring” and “communicating **a result** of said neuromonitoring to a user.” In light of this amendment the Applicants assert that the public should readily understand the scope of what is claimed. Furthermore, the amendment has removed any reference to an earlier limitation such that antecedent basis is not necessary. Applicants thus believe that the rejections under 35 USC 112, second paragraph, are overcome and should be withdrawn. An indication to that effect is earnestly solicited.

### **35USC 103(a)**

On page 3 of the office action, claims 1, 3 5, 11, and 16 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,728,046 to Mayer et al. (“Mayer”) in view of US Patent 6,206,826 to Mathews et al. (“Mathews”). Applicants respectfully traverse these rejections as set forth below.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. In the absence of one or more of these criteria a rejection for obviousness is inappropriate and cannot stand.

Claim 1, as previously presented, is directed towards a system for accessing a surgical target site within a spine. The system includes a distraction assembly, a primary retractor assembly, and a supplemental retractor assembly. The distraction assembly is adapted to create a distraction corridor to the surgical target site. The primary retractor assembly has a handle assembly and a first retractor blade, a second retractor blade, and a third retractor blade removably coupled to the handle assembly. The handle assembly is adapted to simultaneously move the first, second and third retractor blades between a closed position and an open position. The closed position is characterized by the first, second and third retractor blades being positioned generally adjacent to one another. The open position is characterized by the first, second and third retractor blades being positioned generally away from one another. The first, second and third retractor blades are adapted to be introduced simultaneously over the distraction assembly while in the closed position to the surgical target site and thereafter moved to the open position to create and maintain an operative corridor to the surgical target site. The supplemental retractor assembly has an arm with a fourth retractor blade removably coupled to the arm. The arm is adapted to be selectively coupled to the handle assembly of the primary retractor assembly. The fourth retractor blade is adapted to be introduced into the surgical target site and moved to expand the operative corridor.

The Mayer reference appears to be silent with regard to at least one element of independent claim 1. Among other voids, Mayer appears to be completely silent regarding the claimed feature of providing “a primary retractor assembly having a handle assembly and a first retractor blade, a second retractor blade, and a third retractor blade removably coupled to said handle assembly, said handle assembly adapted to move said first, second and third retractor blades between a closed position and an open position, **said closed position being**

**characterized by said first, second and third retractor blades being positioned generally adjacent to one another**, said open position being characterized by said first, second and third retractor blades being positioned generally away from one another” As pointed out by the examiner on pages 3-4 of the office action, the overhead view of Figure 2, shows the system in an open position in which each retractor blade 7, 18, 19 are positioned generally away from each other. However, the Examiner’s further assertion that when the holding arms are extended longitudinally toward the center of the assembly, the system reverts to a closed position where the retractor blades 7, 18, 19 are positioned generally adjacent to one another is neither shown or described in Mayer. Indeed such an assertion is contradicted by the teachings of Mayer.

To insert the retractor of Mayer, bone screws 36 and accompanying extensions 35 are first screwed into adjacent vertebral bodies. Thereafter the retractor is lowered onto the screw extensions by sliding the support feet 39, 40 (also comprising of the retractor body 32) over the screw extensions 35. *Mayer, Col. 3 ln. 42-53*. Alternatively, the support feet 39, 40 may be inserted onto the screw extensions 35 first, and thereafter the rest of the retractor can be attached to the support feet 39, 40. *Mayer, Col. 3 ln. 58-62*. As evident in Figures 1 and 2, when in the open position referred to by the Examiner, the support feet 39 and 40 lie directly in-between and perpendicular to the first retractor blade 7 on one side and the and third retractor blades 18, 19 on the opposing side. Since the support feet 39, 40 are positioned simultaneously (or even before) with the retractor blades 7, 18, 19, the retractor blades would be prevented from assuming a closed position in which the retractor blades are positioned generally adjacent to one another. Mathews also fails to teach a retractor system wherein the primary retractor assembly adapted to move the first, second and third retractor blades between a closed position and an open position wherein the closed position is characterized by “the first, second, and third retractor blades being positioned generally adjacent to one another,” and cannot fill the voids left by Mayer. Because both Mayer and Mathews are silent with regard to at least one element of independent claim 1, the Applicants respectfully submit that the rejection under 35 USC 103(a) should be withdrawn in favor of an indication of allowance which is hereby respectfully requested. Furthermore, claims 3, 5 and 11, being dependent upon and further limiting independent claim 1, should be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional recitations they contain.

Claim 16 is directed to a method of accessing a surgical target site within a spine, comprising the steps of: (a) creating a distraction corridor to the surgical target site; (b) removably coupling a first retractor blade, a second retractor blade, and a third retractor blade to a handle assembly capable of moving said first, second and third retractor blades from a closed position to an open position, said closed position being characterized by said first, second and third retractor blades being positioned generally adjacent to one another and said open position characterized by said first, second and third retractor blades being positioned generally away from one another; (c) simultaneously introducing said first, second, and third retractor blades into said distraction corridor while in said closed position; (d) actuating said handle assembly to open first, second and third retractor blades to create an operative corridor to said surgical target site; (e) coupling a fourth retractor blade to said handle assembly after said first, second, and third retractor blades have been moved to said open position; and (f) moving said fourth retractor blade to expand said operative corridor.

The Mayer reference similarly appears to be silent with regard to at least one element of independent claim 16. Among other voids, Mathews appears to be completely silent regarding the claimed feature of step (b) “removably coupling a first retractor blade, a second retractor blade, and a third retractor blade to a handle assembly capable of moving said first, second and third retractor blades from a closed position to an open position, **said closed position being characterized by said first, second and third retractor blades being positioned generally adjacent to one another** and said open position characterized by said first, second and third retractor blades being positioned generally away from one another, ” and step (c) of “simultaneously introducing said first, second, and third retractor blades into said distraction corridor while in said closed position.” As discussed above, when the first, second, and third retractor blades 7, 18, 19 of Mayer are inserted to the target site, they are separated at least by the width of support feet 39, 40 and thus cannot be said to be in a closed position where the retractor blades are positioned generally adjacent to one another.

Mayer also appears to be silent regarding step (e) of “coupling a fourth retractor blade to said handle assembly **after** said first, second, and third retractor blades have been moved to said open position.” Again, the support feet 39, 40 (comprising the retractor body 32 which the

Examiner considers the fourth retractor blade) are inserted either first or simultaneously with the first, second, and third retractor blades 7, 18, 19. Mathews also appears to be silent with regard to at least the step (b) of “removably coupling a first retractor blade, a second retractor blade, and a third retractor blade to a handle assembly capable of moving said first, second and third retractor blades from a closed position to an open position, **said closed position being characterized by said first, second and third retractor blades being positioned generally adjacent to one another** and said open position characterized by said first, second and third retractor blades being positioned generally away from one another,” step (c) of “simultaneously introducing said first, second, and third retractor blades into said distraction corridor while in said closed position,” and (e) of “coupling a fourth retractor blade to said handle assembly **after** said first, second, and third retractor blades have been moved to said open position,” and again fails to remedy the voids found in the teachings of Mayer. As such, the Applicants respectfully submit that the rejection of claim 16 under 35 USC 103(a) should be withdrawn in favor of an indication of allowance which is hereby respectfully requested.

The remaining claims were rejected under 35 USC 103 as being obvious over Mayer and Matthews and further in view of one of the Luque (US 4,913,134), Arthur (US 972,983), Underwood (US 2001/0056280), Kraus (US 4,611,597), Shin (US 4,226,228), Streeter (US 6,273,905), and Schrom (US 7,047,082) references. As set forth above, Mayer and Mathews fail to teach features of newly independent claims 1 and 16. The additional references listed above do not cure the voids found in the combination of Mayer and Mathews. As such, whether taken alone or in combination, the cited art do not appear to contain any requisite teaching, suggestion or motivation that would have lead someone of ordinary skill in the art to the present invention now claimed. Allowance of all currently pending claims is hereby earnestly solicited.

### **Conclusion**

Favorable consideration and allowance of the claims are respectfully requested. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited. If there any fees or overpayments associated with this amendment or any accompanying paper, the Commissioner is authorized to debit or credit USPTO Deposit Account No. 50-2040.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Respectfully submitted,  
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September 17, 2008